IL 143259

A METHOD FOR MOVING AN OBJECT THROUGH THE COLON

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FIELD OF THE INVENTION

The present invention relates to the field of gastrointestinal diagnosis and therapeutics, and specifically to a method for moving an object through the colon.

BACKGROUND OF THE INVENTION

Objects that are swallowed are moved easily by peristalsis through the small bowel, but their movement in the colon (large intestine) is slow and unpredictable. The colon's main function is to remove (absorb) much of the water from the stool and to store the stool. The colon begins with the cecum, a small saclike evagination, then continues with the ascending colon, from appendix in right groin up to a flexure at the liver, transverse colon, liver to spleen, descending colon, spleen to left groin, then sigmoid (S-shaped) colon back to midline and anus. The colon has three longitudinal muscle bands whose actions assist movement through the colon.

It is sometimes advantageous to move objects through the colon independently of the natural action of the colon muscles. For example, delivery of a medicament to a specific location in the colon may be time dependant and cannot rely on the natural movement in the colon. Also a device for imaging the

colon might benefit from being actively moved through the colon so as to efficiently view the colon.

Current methods of moving objects, especially imaging devices, through the colon involve the use of endoscopes, typically colonoscopes, which are expensive and inconvenient for patient use, and do not always enable to reach distal parts of the colon, namely the right colon and caecum.

SUMMARY OF THE INVENTION

The method of the present invention utilizes high osmotic pressure compositions, such as contrast agents, to assist in the movement of objects through the colon.

The method of the invention, according to one embodiment of the invention includes the steps of: placing an object in a rudimentary part of a patient's gastrointestinal tract, such as by ingesting or by introducing the object via an endoscope; and administering through a rudimentary part of the patient's gastrointestinal tract a suitable amount of a high osmotic pressure composition that is essentially not absorbed from the intestine.

Optionally, the method can include a step of performing a colonoscopic preparation prior to the step of placing the object.

A rudimentary part of the gastrointestinal tract includes parts of the GI tract that are anterior to the small intestine, such as the mouth, esophagus and stomach.

The high osmotic pressure composition that is essentially not absorbed from the intestine, preferably comprising a contrast agent, such as gastrografin, progresses through the colon faster than the object and because of its high osmotic pressure it pushes the object through the colon. The osmotic pressure reverses the flux of fluid through the colon wall and causes the accumulation of fluids within the bowel. Thus the colon is distended which triggers contraction of the smooth muscles similarly to the natural mode of movement in the colon.

Additionally, the forces generated during the fast flow along the colon (during the excretion process) can carry the object.

The object may be any device suitable for being moved through the colon. Preferably, the device is a therapeutic device or a diagnostic device or a combination of both. For example, the device may be an apparatus for administering a medicament to the GI tract including a sustained release medicament in the form of a tablet, capsule, pill, etc. The object may also be a device for imaging the GI tract such as the swallowable capsule described in IL 108352, which is assigned to the common assignee of the present invention and which is hereby incorporated by reference. A swallowable capsule for imaging the gastrointestinal tract preferably includes a camera system, such as a CCD or CMOS imaging camera, an illumination source for illuminating the GI tract and means for transmitting the video output of the camera system to an external receiving system.

The swallowable capsule may be a wireless imaging device. Thus, the invention enables wireless imaging of the colon which was formerly not easily achieved.

The present invention further relates to the use of contrast agents, such as barium sulfate or a mixture of sodium amidotrizoate and meglumine amidotrizoate (gastrografin), in moving objects through a patient's colon.

The present invention further relates to high osmotic pressure compositions that are essentially not absorbed from the intestine for moving an

object through a patient's colon. The composition comprises a contrasting agent and additives such as flavorings and/or wetting agents.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Figure 1 is a schematic illustration of an object being moved in a patient's colon in accordance with an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Contrast agents are used in the present invention, as high osmotic pressure compositions, to move objects in the colon.

The invention can be used to move any suitable object through the colon, as discussed above. In an embodiment of the invention, schematically illustrated in Fig. 1, an imaging device for imaging the GI tract is moved through the colon.

A wireless in vivo imaging device 10 typically comprises an illumination source 12 an optical window 11, through which the light illuminates the inner portions of the GI tract, an imaging camera 13 such as a CCD or a CMOS imaging camera, which detects the images, an optical system (not shown) which focuses the images onto the imaging camera, a transmitter and an antenna (not shown) for transmitting video signals from the imaging camera to an external receiving system, and a power source (not shown), such as a silver oxide battery, that provides power to the entirety of the electrical elements of the device.

The device 10 may also include a compartment for collecting or distributing substances from or to the GI tract (such as that described in WO0022975 which is assigned to the common assignee of the present invention and which is hereby incorporated by reference), such that it can be used for diagnostic and for therapeutic purposes.

The device 10 is ingested by a patient and traverses the small intestine pushed along by natural peristalsis. When the device 10 reaches the cecum 101 it typically remains in the cecum 101 for long periods of time.

A high osmotic pressure composition that is essentially not absorbed from the intestine is administered to the patient and progresses through the small intestine arriving at the cecum 101 for example the osmotic pressure of Gastrografin at 37°C is 55.1 atm and its osmolality is 2.15 (osm/kg H_2O). The composition progresses in the colon in the direction shown by arrows 111 faster than the device 10, pushing, in its progression device 10 through the different parts of the colon 102.

If left to the natural action of the colon muscles, device 10 would move slowly and erratically through the colon 102 depleting the device power while prossibly being unable to obtain a sufficient number of images for efficiently monitoring and diagnosing the colon. Thus, the invention enables wireless imaging of the colon which was formerly not easily achieved.

A wireless swallowable capsule as described above was administered under Helsinki Committee guidelines to normal healthy volunteers in the standard fashion. The volunteer underwent standard colonoscopic preparation consisting of a 24-hour liquid diet and 4 ounces of Fleet phosphasoda the evening before and the morning of the procedure. The volunteer was encouraged to drink a large volume of fluid before and after ingestion of the capsule. The passage of the capsule was monitored, using the on-line configuration of the receiving system. The volunteer was given 8 ounces of gastrografin diluted as for regular body CT examination [5%], every 15 minutes starting 2.5 hours after ingestion of the capsule, up to a total of 2 liters. The volunteer was allowed to eat a normal meal 4 hours after ingestion of the capsule.

Results: In one case, the gastric emptying time was 42 minutes, and the capsule reached the cecum after 4 hours, 16 minutes. The capsule was excreted from the colon 22 hours after ingestion. Images of various parts of the colon were acquired for more than 3 hours. In the second case, gastric emptying occurred after 8 minutes, and the capsule reached the cecum after 8 hours. Images of all parts of the colon were acquired for 2.5 hours. The capsule was excreted after 10.5 hours, still working.

Conclusion: The first successful passage through the right colon in the first case and the entire colon in the second case of a functioning capsule endoscope using a novel technique is described. The use of gastrografin was based on clinical observation in GI radiological procedures, such as CT. This agent has a very important role to play in the movement of the imaging capsule through the colon.

Gastrografin contains a mixture of sodium amidotrizoate and meglumine amidotrizoate in a proportion of 10:66 (amidotrizoic acid or diatrizoic acid: 3,5-bis-acetamido-2,4,6-triiodobenzoic acid). 1 mL Gastrografin contains sodium amidotrizoate 100,00 mg and meglumine amidotrizoate 660,00 mg (sodium diatrizoate and meglumine diatrizoate) in aqueous solution plus flavourings and a wetting agent. The contrast-giving substances in Gastrografin are salts of amidotrizoic acid in which the X-ray absorbing iodine is present in stable chemical bond.

Following oral administration only about 3% of the amidotrizoic acid is absorbed from the stomach and intestines. This portion is eliminated mainly via the kidneys.

Gastrografin can be used either orally or as an enema. Gastrografin travels through the colon faster than the capsule and is a clear fluid, allowing a clear view of the colon. Another advantage of gastrografin is its opacity to x-ray, allowing direct view in fluoroscopy and enabling monitoring of the passage of the capsule through the GI tract.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims which follow:

CLAIMS

1. A method for moving an object through a colon comprising the steps of:

placing an object in a rudimentary part of a patient's gastrointestinal tract; and

administering through a rudimentary part of the patient's gastrointestinal tract a suitable amount of a high osmotic pressure composition that is essentially not absorbed from the intestine.

2. The method according to claim 1 further comprising a step of performing a colonoscopic preparation prior to the step of placing the object.

3. A method according to claim 1 wherein a rudimentary part of a patient's gastrointestinal tract comprises the mouth, the esophagus or the stomach.

4. A method according to claim 1 wherein the step of placing an object is performed by ingesting the object.

5. A method according to claim 1 wherein the step of placing an object is performed by introducing the object into a rudimentary part of the gastrointestinal tract via an endoscope.

6. A method according to claim 1 wherein the object is bein placed in a distal part of the colon (right colon, caecum) by a colonoscope (through the anus).

7. A method according to claim 1 wherein the object is a diagnostic or therapeutic device or a device that is both diagnostic and therapeutic for monitoring or treating or for monitoring and treating the gastrointestinal tract.

8. A method according to claim 1 wherein the object is a device for sustained release of medicaments to the colon.

9. A method according to claim 1 wherein the object is an in vivo imaging device.

10. A method according to claim 1 wherein the high osmotic pressure composition comprises a contrasting agent.

11. A method according to claim 1 wherein the high osmotic pressure composition comprises gastrografin or barium sulfate.

12. A method according to claim 1 wherein the step of administering a high osmotic pressure composition comprises administering 8 ounces of gastrografin diluted to about 5%, in predetermined time intervals after placing of the object, up to a total of 2 liters.

13. A method according to claim 11 wherein the predetrmined time intervals are every 15 minutes starting from about 2.5 hours after placing of the object.

14. Use of contrasting agents in the preparation of a high osmotic pressure composition that is essentially not absorbed from the intestine for moving an object in a patient's colon.

15. The use according to claim 13 wherein the contrasting agent is gastrografin or barium sulfate.

16. The use according to claim 13 wherein the high osmotic pressure composition that is essentially not absorbed from the intestine moves an

object through a patient's colon by being administered to a patient through a rudimentary part of the patient's gastrointestinal tract after the object has been placed in a rudimentary part of the patient's gastrointestinal tract.

17. The use according to claim 13 wherein the object is a diagnostic or therapeutic device or a device that is both diagnostic and therapeutic for monitoring or treating or for monitoring and treating the gastrointestinal tract.

18. The use according to claim 13 wherein the object is a device for sustained release of medicaments to the colon.

19. The use according to claim 13 wherein the object is an in vivo imaging device.

20. A high osmotic pressure composition that is essentially not absorbed from the intestine for moving an object through a patient's colon comprising a contrasting agent and additives.

21. A composition according to claim 19 wherein the contrasting agent is gastrografin or barium sulfate.

22. A composition according to claim 19 wherein the additives comprise flavorings and/or wetting agents.

23. A method for wireless imaging of the colon comprising the steps of

placing a wireless in vivo imaging device in a rudimentary part of a patient's gastrointestinal tract;

administering through a rudimentary part of the patient's gastrointestinal tract a suitable amount of a high osmotic pressure composition that is essentially not absorbed from the intestine, thereby moving the in vivo imaging device through the colon; and

activating the in vivo imaging device to obtain images of the colon.

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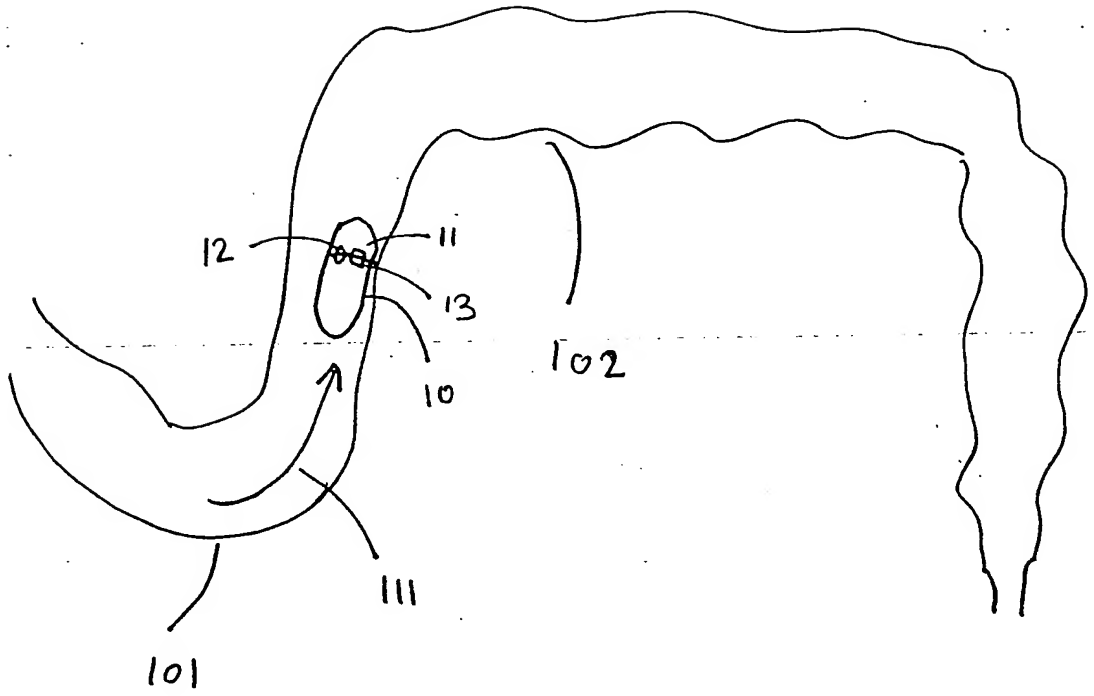
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